

K081181

510(K) Summary

MAY - 5 2008

Submitter: Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: April 24, 2008

Device Trade Name: Smart CO₂

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.4810

Equivalent Device: Lumenis OpusDent Family laser and Millennium Dental Technologies PerioLase Dental Laser

Device Description: Smart CO₂ is a CO₂ laser, having a sealed CO₂ gas tube as the lasing medium. It is a laser with a wavelength of 10.6 μm.

Laser activation is by foot switch. Overall weight of the laser is 25 Kg, and the size is 180x62x42 cm (HxWxD).

Electrical requirement is 110 VAC, 15A, 50-60 Hz, single phase.

Intended Use: The Smart CO₂ laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues. It is also indicated for laser assisted new attachment procedure.

Comparison: The Smart CO₂ laser is substantially equivalent to the predicate devices. They have the same principle of operation and essentially the same power range and the same indications for uses.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Smart CO₂ laser is another safe and effective device for body soft tissue, including intraoral soft tissue applications.

Additional Information: none



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2008

Cynosure, Inc.
% Mr. George Cho
Sr. VP, Medical Technology
5 Carlisle Road
Westford, Massachusetts 01886

Re: K081181

Trade/Device Name: Smart CO₂ ((Smart US 20 D / UltraSpeed, Smart Clinic and
PerioPulse) Laser

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology

Regulatory Class: II

Product Code: GEX

Dated: April 24, 2008

Received: April 25, 2008

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081181

Device Name: Smart CO₂ ((Smart US 20 D / UltraSpeed, Smart Clinic and PerioPulse) Laser

Indications For Use:

The Smart US 20 D / UltraSpeed and Smart Clinic laser is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology, neurosurgery, oculoplastic, orthopedic, pulmonary/thoracic surgery, and urology for surgical and aesthetic applications.

Also, the Smart CO₂ surgical laser is indicated for periodontal applications such as, but not limited to:

- Removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement)
- Biopsies
- Frenectomy, Frenum release
- Gingivoplasty
- Papillectomy
- Vestibuloplasty
- Hyperplasia
- Operculectomy
- Drainage (abscess)
- Flap surgery
- Fibroma (nonmalignant tumor, mucosa, tongue)
- Epulis
- Aphthous ulcers
- Removal of soft tissue, cysts, and tumors
- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

The PerioPulse laser is indicated for the removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement). It is also indicated for laser assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium)

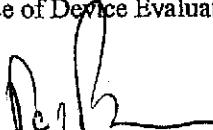
Prescription Use
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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